K072575 #1/2

510(k) Summary of Safety and Effectiveness for the
Triathlon® Screw-Fixation Tibial Baseplate

JAN - 7 2008

Proprietary Name:	Triathlon® Screw-fixation Tibial Baseplate
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Name and Reference	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. 21 CFR §888.3565
Regulatory Class:	Class II
Device Product Code:	87 MBH - prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer,
For Information contact:	Francisco Haro Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07432 Phone: (201) 831-5493 Fax: (201) 831-6038 E-Mail: Frank.Haro@stryker.com
Date Summary Prepared:	December 6, 2007

Device Description

The tibial baseplates of the Triathlon® Total Knee System has been modified to include a screw-fixation option for use with existing Triathlon® Total Knee components. The subject tibial baseplate is porous coated and will be available with and without Howmedica Osteonics' Peri-apatite (PA) coating. The Triathlon® fixed bearing cementless tibial baseplates are compatible with Triathlon® CR, PS, and CS tibial inserts and patellae. The Triathlon® components proposed in this submission are manufactured from cast cobalt chrome and have a cobalt chrome porous coating, available with and without a peri-apatitie coating. The Triathlon® tibial component is fixed bearing and will be provided in sizes 1 through 8. Compatible cobalt chrome bone screws are also included in this submission in 6.5mm diameter with lengths of 16mm, and 20mm to 60mm in 5mm increments.

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Intended Use:

The Triathlon® Screw-fixation tibial baseplates are intended for use in primary and revision total knee arthroplasty to alleviate pain and restore function. All total knee components presented in this submission are provided sterile for single-use.

Indications

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

Additional Indications for Posterior Stabilized (PS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

The Triathlon® Screw-fixation Tibial Baseplates are intended for cementless use only.

Substantial Equivalence:

The determination of the substantial equivalence of the Triathlon® Screw-fixation tibial baseplate is based on its similarities in intended use, design and sterilization to Howmedica Osteonics' Triathlon® Total Knee System (K051380, cleared 30 August 2005) and Duracon® Total Knee System (K032418 cleared, 11 September 2003).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2008

Stryker Orthopaedics
% Mr. Francisco Haro
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, NJ 07430

Re: K072575
Trade/Device Name: Triathlon Screw-Fixation Tibial Baseplate
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: December 6, 2007
Received: December 7, 2007

Dear Mr. Haro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K072575

Device Name: Triathlon® Screw-fixation Tibial Baseplate

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The Triathlon® Screw-fixation Tibial Baseplates are intended for cementless use only.

Prescription Use X OR Over-the-Counter Use
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072575